

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Hector Knight Castro et al.

Art Unit 1618

Serial No. 10/510,454

Filed: October 4, 2004

Confirmation No. 2287

For: METHOD FOR OBTAINING A 2-18F-FLUOR-2-DEOXY-D-GLUCOSE
18F-FDG-SOLUTION

Examiner: Melissa Jean Perreira

October 16, 2009

PRE-APPEAL BRIEF REQUEST FOR REVIEW

TO THE COMMISSIONER FOR PATENTS,

SIR/MADAM:

Applicants hereby request review of the Office's rejection of claims 1, 2, 5 and 16-18, as set forth in the final Office action dated July 16, 2009 and the subsequent Advisory Action dated September 23, 2009.

A. Status of the Claims and Claim Rejections

Claims 1, 2 and 5-18 are pending. Claims 6-15 were previously withdrawn for being directed to a non-elected species and/or invention. However, in view of the claim amendments previously made to these claims (see Amendment D, submitted May 26, 2009), all claims now depend directly or indirectly from claim 1. Applicants therefore requested that claims 6-15 be rejoined and examined.

The Office withdrew the previous rejection of the claims under 35 U.S.C. §112, second paragraph. Accordingly, the issue on appeal, for which Applicants request review, is whether claims 1, 2, 5 and 16-18 are obvious under 35 U.S.C. §103(a) over the PET-Radiopharmaceutical Dispensing Unit Manual, Nuclear Interface GmbH ("the Manual"), including the Supplement FDG Synthesizers ("the Supplement") in view of Damhaut et al. (U.S. Patent No. 6,172,207) and further in view of Asai et al. (U.S. Patent No. 5,536,491) and Stone-Elander et al. (U.S. Patent No. 5,308,944). In particular, Applicants request review of the prior art status of the Manual and the Supplement.

B. Arguments in Support of Patentability of the Claims

Reconsideration is requested of the rejection of claims 1, 2, 5 and 16-18 as obvious under 35 U.S.C. §103(a) over the PET-Radiopharmaceutical Dispensing Unit Manual, Nuclear Interface GmbH ("the Manual"), including the Supplement FDG Synthesizers ("the Supplement") in view of Damhaut et al. (U.S. Patent No. 6,172,207) and further in view of Asai et al. (U.S. Patent No. 5,536,491) and Stone-Elander et al. (U.S. Patent No. 5,308,944).

Applicants submit that the Office has failed to establish the Manual and the Supplement are prior art against the pending claims. Specifically, Applicants submit that: (1) the Manual and the Supplement are not prior art unless they were **actually distributed**; (2) it is the **Office's burden** to establish that the Manual and Supplement were **actually distributed**; (3) the contact information provided in the Manual (including the phone number, fax number, website address and email address) is **irrelevant** to the question of whether the Manual and the Supplement were **actually distributed**; and, (4) the listing of the Manual and the Supplement in an Information Disclosure Statement is not an admission that the reference is prior art against the claims. Applicants' positions are clearly supported by applicable case law, by the Code of Federal Regulations (CFR), and by the MPEP.

1. The Manual and Supplement must have been Actually Disseminated

The Office has cited the Manual as the principal reference in its rejection of the pending claims as obvious under 35 U.S.C. §103(a). In Amendment C dated January 5, 2009, Applicants first argued that the Office had not established that the reference was actually disseminated or made available to the public (see p. 5). The Office responded by stating that the manual "would be" distributed to those who purchase the laboratory equipment (see Office action dated February 25, 2009, notes 14-15). Applicants noted in Amendment D dated May 26, 2009 that it is not relevant whether the reference "would be distributed"; rather, the Office must establish that the reference was **actually distributed**. This standard for determining whether a reference may be considered to be prior art is supported by both case law and the MPEP. "A reference is proven to be a "printed publication" "upon a satisfactory showing that such document **has been disseminated or otherwise made available** to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." (See MPEP §2128.)

Accordingly, it is not enough for the Office to show that the document is a **type** of document that is distributed to those that purchase the dispensing unit; rather, the Office must show that the manual itself was **actually disseminated or distributed**.

2. It is the Office's Burden to Establish Actually Dissemination

In Amendment D dated May 26, 2009 (see p. 6), Applicants pointed out that the Manual was submitted during prosecution of the corresponding European application without any details or supporting documentation relating to its origin (i.e., relating to when or if it was distributed), and further that this **does not** equate to a finding that the document was disseminated or distributed (which the European Patent Office concluded, as well). In addition, Applicants have provided a number of hypothetical scenarios that would explain the existence of these documents that would not involve their disseminated or distribution. (See Applicants' Amendment D, pages 6-7.)

The Office responded in the July 16, 2009 Office action by stating that the scenarios are opinions of the Applicants and not based on any evidence (see note 10 therein).

Applicants submit that **it is not Applicants' burden** to establish that the document was not distributed; rather, **it is the Office's burden** to establish that the document was **actually distributed or disseminated**, and thus that one of these hypothetical scenarios did not occur. Applicants' position is clearly supported by case law and the MPEP. (See Applicants' Amendment D at page 6, citing MPEP §2128, which in turn cites *In re Wyer*, 655 F.2d 221, 227, 210 USPQ 790, 795 (CCPA 1981), this case stating that "the one who wishes to characterize the information, in whatever form it may be, as a 'printed publication' . . . should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art".)

Accordingly, the Office's opinion that the scenarios presented by the Applicants are merely hypothetical is **not relevant** to the issue. **The Office must establish** that the documents were **actually distributed**, and it has simply failed to do so, as further detailed below.

3. The Contact Information Provided in the Manual is Irrelevant

The only evidence put forth by the Office as to the prior art status of the Manual and the Supplement is that the Manual includes contact information, including a phone number, fax number, website address and email address (see Office action dated July 16, 2009, note 11). The Office submits that this contact information shows the Manual and Supplement were distributed to those skilled in the art that would need such information. The Office's position concerning this contact information **directly conflicts** with established case law, as further detailed below. (See also Applicants' Letter in Response to Final Action submitted September 16, 2009 at page 3.)

In the case of *Resqnet.com, Inc., v. Lansa, Inc.* (533 F.Supp.2d 397), the alleged infringer argued that the patent at issue was invalid for being described in a printed publication before the critical date. The references at issue were a **user manual** that had a date of October 1991 on its first page and a **tutorial** that had a copyright date of 1993. According to the court, "no witness testified, nor was any evidence presented, that either of these documents was ever published or disseminated to the public." (*Id.* at 414.) As a result, the court held that, in the **absence** of such evidence that the user manual and the tutorial were **actually** published or made public prior to the critical date, the references **could not** be considered prior art. (*Id.*)

Accordingly, consistent with the holding of the *Resqnet.com* case, the fact that the Manual includes the noted contact information is **clearly not evidence** that the reference was **actually disseminated** or otherwise made available.¹

¹ As noted on page 7 of Applicants' Amendment D, although not precedential, this outcome is consistent with the position taken by European Patent Office (EPO), which held "[the manual] cannot be considered as having been made available to the public."

4. Citing the Manual and Supplement in an IDS is not an Admission

The Office further asserts that citation of the Manual and Supplement in an IDS (Information Disclosure Statement) is an admission by Applicants that the reference is considered material to patentability of the claims (see July 16, 2009 Office action, note 10; Advisory Action, Continuation Sheet). Applicants submit the Office is simply wrong, inasmuch as **the Office's position is clearly contrary to the MPEP, the Code of Federal Regulations and case law (i.e., the Resqnet.com case cited above).**

Specifically, Applicants note that 37 CFR 1.97(h) unequivocally states, “[t]he filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).” The MPEP adds that the “[m]ere listing of a reference in an information disclosure statement is not taken as an admission that the reference is prior art against the claims.” (MPEP §2129(IV).) Additionally, it is to be noted that the alleged infringer in *Resqnet.com* argued that submission by the patent owner of the references at issue in the case in an IDS during reexamination was an admission that the references were publicly disseminated. In response thereto, the court stated the “**mere submission of an IDS to the USPTO does not constitute the patent Applicant's admission that any reference is in the IDS is prior art.**”² Further, according to the court, submission of the reference in the IDS **does not speak to the dissemination of the reference prior to the critical date.**

5. The Claimed Subject Matter is Not Obvious

The details of claim 1, from which all other pending claims depend, as well as the disclosure provided by Damhaut et al., Asai et al., and Stone-Elander et al., and Applicants' position with respect to why the claim subject matter is not obvious in view of the disclosure provided by these references, are set forth in Applicants' Amendment D submitted May 26, 2009 (pages 8-10 therein), as well as in Applicants' Letter in Response to Final Action submitted September 16, 2009 (pages 4-6 therein). However, in brief, Applicants submit that, for the reasons set forth above, the Office's primary references (i.e., the Manual and Supplement) do not qualify as prior art here. Absent the Manual and Supplement, the Office has clearly failed to establish a *prima facie* case of obviousness,

In particular, the circumstances of the alleged distribution (prior use) have not been sufficiently substantiated. Therefore the examining division does not intent to further investigate the matter.”

² See Applicants' Letter in Response to Final Action submitted September 16, 2009 at page 4 (citing *Resqnet.com*, 533 F.Supp.2d 397, 414, note 5 therein, emphasis added). In this regard please note that, in the Letter, Applicants mistakenly attributed this statement to a position taken by the USPTO during a reexamination proceeding. It was actually the Court in *Resqnet.com* who made the noted statement.

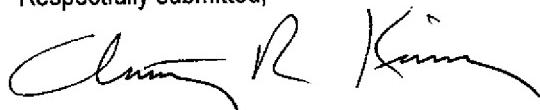
because the Office has failed to show how the remaining combination of references disclose or suggest each and every element of the subject matter of claim 1, or how one of ordinary skill in the art would be motivated to modify or combined the remaining references in order to arrive at the subject matter of claim 1.

C. Conclusion

In view of the foregoing, favorable consideration and allowance of all pending claim in the present application are respectfully requested.

The Commissioner is authorized to charge any fees that may be due for this Pre-Appeal Brief Request for Review, as well as the Notice of Appeal being filed simultaneously herewith, to Deposit Account No. 13-1160.

Respectfully submitted,



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